DRUG REFORM
AND
THE OVER THE COUNTER INDUSTRY

BY HENRY A. WAXMAN, CHAIRMAN
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

TO THE

ANNUAL MEETING OF
THE PROPRIETARY ASSOCIATION
WHITE SULFUR SPRINGS, WEST VIRGINIA

MAY 11, 1980

GOOD MORNING. IT IS HARD FOR ME TO BELIEVE THAT ONE YEAR WILL HAVE PASSED, AS OF TOMORROW, SINCE I SPOKE WITH YOU. THIS ANNUAL MEETING PRESENTS A WONDERFUL OPPORTUNITY TO ME TO RENEW ACQUAINTANCES WITH YOU. THE ONLY PROBLEM I HAVE WITH ANNUAL MEETINGS IS THAT THEY REMIND US OF HOW QUICKLY TIME PASSES, AND DARE I SAY IT, OF HOW MUCH OLDER WE ARE.

MY FAMILY AND I HAVE THOROUGHLY ENJOYED THIS WEEKEND WITH YOU. I WANT TO GIVE SPECIAL THANKS TO YOUR PRESIDENT JIM COPE, AND TO THE MEETING MANAGER, NANCY O'MALLEY FOR THEIR ASSISTANCE IN MAKING OUR TRIP OVER QUITE CONVENIENT AND MAKING OUR STAY MOST ENJOYABLE.

MY FIRST YEAR AS CHAIRMAN OF THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT HAS BEEN EVENTFUL AND QUITE PRODUCTIVE. AS MANY OF YOU KNOW MY SUBCOMMITTEE AND COMMITTEE ARE ABOUT TO COMPLETE THE ANNUAL PROCESS OF REAUTHORIZING THOSE HEALTH PROGRAMS WHICH WOULD OTHERWISE TERMINATE AT THE END OF THIS CURRENT FISCAL YEAR. I AM PLEASED TO TELL YOU TODAY THAT MY SUBCOMMITTEE WILL BEGIN HEARINGS IN LATE JUNE ON ALL LEGISLATIVE PROPOSALS TO REWRITE THE DRUG SECTION OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT. THE SCOPE OF THESE HEARINGS WILL BE AS BROAD AS THE DRUG LAWS THEMSELVES. THEY WILL BE CONDUCTED SO THAT OUR MEMBERS WILL NOT ONLY LEARN WHAT THE LEGISLATIVE ISSUES ARE, BUT SO THAT WE WILL ALSO HAVE THE OPPORTUNITY TO EXPLORE IN DEPTH WHO THE DRUG INDUSTRY IS, THE WAYS YOU ARE MEETING THE PUBLIC'S DEMAND AND NEED FOR DRUGS, AND THE INCENTIVES AND DISINCENTIVES WHICH ENCOURAGE YOU TO SERVE THE PUBLIC WELL.

I DO NOT ANTICIPATE ENACTMENT OF A COMPREHENSIVE DRUG REFORM PROPOSAL THIS YEAR. UNLIKE THE SENATE COMMITTEE WE HAVE NOT HAD THE YEARS OF INVOLVEMENT WITH THIS COMPLEX AND IMPORTANT AREA. REMEMBER THAT ABOUT HALF OF THE MEMBERS OF THE SUBCOMMITTEE JOINED THE PANEL IN THIS CONGRESS. THAT MEANS THAT OVER HALF MY SUBCOMMITTEE WAS NOT IN THE CONGRESS WHEN WE DRAFTED THE MEDICAL DEVICES LEGISLATION A FEW SHORT YEARS AGO, OR EVEN WHEN WE STARTED CONSIDERATION OF THE ADMINISTRATION'S DRUG BILL IN THE LAST CONGRESS WHEN PAUL ROGERS WAS SUBCOMMITTEE CHAIRMAN.

THE YEAR SINCE I LAST SAW YOU HAS BEEN PRODUCTIVE FOR ME BECAUSE I'VE HAD THE OPPORTUNITY TO EXPLORE AND DEVELOP DIFFERENT PERSPECTIVES ON WHAT CONTRIBUTES TO THE HEALTH OF OUR CITIZENS. I WOULD LIKE TO SHARE FOUR OF THEM WITH YOU.

IN CONSIDERING THE REAUTHORIZATION OF THE NATIONAL INSTITUTES OF HEALTH I HAVE GAINED A NEW APPRECIATION FOR THE CREATIVITY AND EXPANSIVENESS OF OUR BIOMEDICAL RESEARCH COMMUNITY AND A NEW RESPECT FOR ITS CONTRIBUTIONS TO OUR GOOD HEALTH.

IF WE HAD A SCIENTIFIC OLYMPICS AS WE DO FOR SPORTS, WE ALL KNOW AMERICANS WOULD WALK AWAY WITH "THE GOLD" FOR ITS UNPRECEDENTED INVESTMENT IN THE DEVELOPMENT OF NEW DRUGS, MEDICAL DEVICES AND NEW TECHNOLOGY. MORE DRUG PRODUCTS, IN MORE VARIATIONS, SIZES OR DOSES ARE AVAILABLE THAN EVER BEFORE IN THE AMERICAN MARKET PLACE. THE PRODUCTIVITY OF THE DRUG INDUSTRY

CONTINUES TO BE HIGHER THAN MANY OTHER KEY SEGMENTS OF OUR ECONOMY.

WE HAVE WATCHED SCIENCE BECOME ONE OF OUR HIGHEST EDUCATIONAL PRIORITIES. CONCERN WITH "KEEPING OUR EDGE" IN THE INTERNATIONAL COMMUNITY HAS MEANT SCIENTIFIC TRAINING IS GIVEN TREMENDOUS IMPORTANCE IN SCHOOL CURRICULA, IN COLLEGE AND GRADUATE SCHOOL ENTRANCE REQUIREMENTS, AND IN THE FUNDING OF AMERICA'S GREATEST UNIVERSITIES AND MEDICAL CENTERS THAT DEVOTE FACULTY AND LABORATORY RESOURCES TO SCIENTIFIC RESEARCH.

THIS EXPLOSION OF SCIENTIFIC RESEARCH AND MEDICAL TECHNOLOGY HAS HAD A TREMENDOUS IMPACT ON OUR SOCIETY. IT'S NOT OFTEN SAID, BUT IT NEEDS SAYING: THANKS TO THE ENORMOUS INVESTMENT WE WERE WILLING TO MAKE IN DRUG RESEARCH, TREMENDOUS ADVANCES IN PUBLIC HEALTH HAVE BEEN MADE.

THE CHALLENGE OF THE 1980's IS A CONTINUING ONE TO FIND INCENTIVES FOR THE DRUG INDUSTRY TO CARRY ON VITAL RESEARCH AND DEVELOPMENT. WE MUST CREATE AND MAINTAIN THE CLIMATE THAT NURTURES PRODUCTIVE RESEARCH AND DEVELOPMENT OF NEW DRUGS AND CONTINUING INNOVATION. WE MUST BE MORE AWARE TODAY THAN EVER BEFORE THAT GOVERNMENT, EVEN ACTING WITH GOOD INTENTIONS, CAN DESTROY INCENTIVES IN OUR PRIVATE SECTOR THROUGH EXCESSIVE AND MINDLESS REGULATION.

A SECOND AND ENTIRELY DIFFERENT PERSPECTIVE ON OUR HEALTH STATUS CAME DURING MY SUBCOMMITTEE'S OVERSIGHT HEARINGS ON THE CLEAN AIR ACT. THOSE HEARINGS MADE ME MORE AWARE OF THE DIFFICULTIES WE FACE IN EVALUATING THE CONSEQUENCES FOR OUR HEALTH OF ENVIRONMENTAL REGULATION.

I AM DEEPLY CONCERNCED ABOUT THE HIGH COST WE ARE IMPOSING ON AMERICAN INDUSTRY AND ULTIMATELY THE AMERICAN CONSUMER, WITH LEGISLATION SUCH AS THE CLEAN AIR ACT, WHICH COMPELLED AUTOMOBILE MANUFACTURERS AND OTHER INDUSTRIES TO DEVELOP AND INSTALL NON-POLLUTING TECHNOLOGY; THE CLEAN WATER ACT, WHICH CURBS INDUSTRIAL AND MUNICIPAL DISCHARGES INTO OUR NATION'S RIVERS; THE OCCUPATIONAL SAFETY AND HEALTH ACT, WHICH PROTECTS WORKERS FROM INJURY ON THE JOB; AND THE SAFE DRINKING WATER ACT WHICH ASSURES ALL AMERICANS A HEALTHY SUPPLY OF TAP WATER AND WHICH PROTECTS GROUND WATER RESOURCES FOR FUTURE GENERATIONS. I AM EQUALLY CONCERNED HOWEVER, WITH THE INCREASINGLY HIGH, BUT UNMEASURABLE, COSTS TO OUR CITIZENS OF SHORTENED AND STUNTED LIVES DUE TO AIR AND WATER POLLUTION AND OCCUPATIONAL AND ENVIRONMENTAL HAZARDS. A RECENT STUDY BY THE CENTER FOR POLICY ALTERNATIVES OF THE MASSACHUSETTS INSITUTE OF TECHNOLOGY ESTIMATES THAT THE BENEFITS TO CONSUMERS OF REGULATING AIR POLLUTION RANGE FROM $5 TO $58 BILLION PER YEAR. IT IS DIFFICULT TO CONSIDER THE COSTS AND BENEFITS OF OUR ENVRIONMENTAL LAWS WHEN THE BENEFIT SIDE--IMPROVED HEALTH STATUS--IS SO HARD TO MEASURE.

I FIND I AGREE, THOUGH, WITH A RECENT SURVEY BY THE WELL KNOWN POLLING ORGANIZATION OF YANKELOVICH, SKELLY AND WHITE. IT CONCLUDES THAT AMERICANS DO NOT WANT TO TRADE ENVIRONMENTAL PROTECTION FOR OTHER OBJECTIVES. THE SAME SURVEY SUGGESTS THAT ANY WEAKENING OF THE NATION'S RESOLVE TO SOLVE ENVIRONMENTAL AND HEALTH ISSUES WILL ONLY BE TEMPORARY: THAT AMERICANS ARE COMMITTED OVER THE LONG TERM TO THE CAUSE OF PROTECTING AND ENHANCING PUBLIC HEALTH.

WHEN MY SUBCOMMITTEE AND COMMITTEE CONSIDERED HOSPITAL COST CONTAINMENT LEGISLATION I GOT A VERY REVEALING LOOK AT OUR NATION'S HOSPITALS AND THEIR IMPORTANT CONTRIBUTIONS TO OUR HEALTH. I DON'T DOUBT FOR A MOMENT THAT OUR HOSPITAL'S DELIVER THE FINEST MEDICAL CARE IN THE WORLD, BUT IT IS CLEAR THAT OUR HOSPITAL SYSTEM OPERATES WITHOUT COST RESTRAINTS. THE RESULT HAS BEEN EXPENSIVE DUPLICATION OF HOSPITAL SERVICES. UNDER OUR MEDICARE AND MEDICAID COST REIMBURSEMENT SYSTEMS, THE MORE A HOSPITAL SPENDS THE MORE REVENUE IT EARNS. THE RESULT HAS BEEN THAT IN THE SHORT FIVE YEAR PERIOD FROM 1978 TO 1983, THE AVERAGE ANNUAL HEALTH CARE COST BILL FOR A FAMILY OF FOUR WILL RISE FROM $2,000 TO $3,600. THERE ARE LIMITS ON WHAT WE CAN SPEND. I AM CONVINCED THAT OUR HEALTH WILL EVENTUALLY SUFFER IF WE DON'T CONTAIN THE COST OF PROVIDING IT.

AND ON WEDNESDAY, MY COMMITTEE COMPLETED IT'S CONSIDERATION AND FAVORABLY REPORTED TO THE HOUSE OF REPRESENTATIVES A BILL REAUTHORIZING OUR HEALTH MANPOWER PROGRAMS FOR THREE ADDITIONAL YEARS. IN THAT LEGISLATION WE HAVE HAD TO FORGE SOLUTIONS TO PROBLEMS WHICH, SEEMINGLY, SHOULD NOT OCCUR AT THE SAME TIME. WE EXPECT, IN 1990 AN OVERSUPPLY OF PHYSICIANS IN SOME URBAN AND ALMOST ALL SUBURBAN AREAS AND A DRAMATIC UNDERSUPPLY IN INNER CITY AND RURAL AREAS. SOME PREDICT THAT WE WILL HAVE AS MAY AS 130,000 EXCESS PHYSICIANS IN THE UNITED STATES IN 1990, BUT THAT AT THE SAME TIME SOME RURAL COMMUNITIES WILL HAVE NO MORE THAN 1 PHYSICIAN FOR 5,000 PEOPLE.

WHEN MY SUBCOMMITTEE BEGINS DRUG HEARINGS IN LATE JUNE WE WILL HAVE THE OPPORTUNITY TO DEVELOP YET ANOTHER PERSPECTIVE ON OUR NATION'S HEALTH. WHAT DO OVER-THE-COUNTER DRUGS CONTRIBUTE TO OUR HEALTH AND HOW SHOULD WE REGULATE THEM? ACCORDING TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, ONLY 9% OF HEALTH EXPENDITURES ARE FOR DRUGS AND OF DRUG EXPENDITURES ONLY ONE DOLLAR IN THREE IS FOR OVER-THE-COUNTER PRODUCTS. WHILE EXPENDITURES FOR OVER-THE-COUNTER PRODUCTS ARE BUT A SMALL PART OF THE TOTAL, I BELIEVE THE PROPER USE OF OVER-THE-COUNTER DRUGS CAN YIELD SUBSTANTIAL SAVINGS. BY EXPERIENCE AND COMMON SENSE WE KNOW THAT PEOPLE ARE ABLE TO MANAGE MANY MINOR HEALTH PROBLEMS WHICH DO NOT WARRANT THE ATTENTION OF HEALTH PROFESSIONALS.

EVEN IN THIS AGE OF RAPID SCIENTIFIC AND TECHNOLOGICAL CHANGE I BELIEVE WE ALL ACCEPT THE NOTION THAT ORDINARY PEOPLE CAN DO A GREAT DEAL TO PROTECT AND PRESERVE THEIR OWN HEALTH. TO THE EXTENT

WE CAN TAKE CARE OF OURSELVES, WE HAVE CONTRIBUTED TO OUR OWN PSYCHOLOGICAL AND PHYSICAL WELL BEING AND HAVE SAVED MONEY AS WELL.

IN MY SUBCOMMITTEE'S REVIEW OF OUR DRUG LAWS AND OF THE DRUG INDUSTRY, I EXPECT TO CAREFULLY EXPLORE A NUMBER OF VERY IMPORTANT ISSUES.

CAN WE IMPROVE THE SPEED AND EFFICIENCY OF OUR DRUG APPROVAL PROCESS WHILE ALWAYS ASSURING THE SAFETY AND EFFICACY OF EVERY NEW DRUG? THIS DELICATE BALANCE MUST BE ACHIEVED WHILE WE ENCOURAGE INCREASED INVESTMENT IN RESEARCH AND DEVELOPMENT AND AN INCREASED RATE OF INNOVATION IN NEW DRUGS.

CAN WE MAKE OUR DRUG APPROVAL PROCESS MORE PREDICTABLE AND DEPENDABLE IN BOTH THE IND AND NDA PHASES? CAN WE GET IMPORTANT BREAKTHROUGH DRUGS ON THE MARKET MORE QUICKLY SINCE THAT IS CLEARLY IN THE PUBLIC'S INTEREST? CAN WE DISCERN THE CURRENT REGULATORY REQUIREMENTS WHICH ARE INEFFECTIVE AND UNNECESSARY AND CAN WE SIMPLIFY OUR REGULATORY PROCESS.

AS WE REVIEW AND REVISE OUR DRUG LAWS WE MUST RETAIN THE PUBLIC'S CONFIDENCE IN THE SAFETY AND EFFICACY OF OUR DRUGS, BOTH WHEN THEY ARE INTRODUCED AND THROUGHOUT THE LIFE OF THE DRUG. CONSUMERS ASSUME THERE IS CONSTANT SURVEILLANCE OF THE DRUGS THEY DEPEND UPON SO FAITHFULLY.

WHILE THE ISSUES I HAVE MENTIONED IMPACT UPON YOUR INDUSTRY LET ME TURN TO THOSE ISSUES WHICH I KNOW ARE OF PARTICULAR CONCERN TO OVER-THE-COUNTER DRUG MANUFACTURERS. THE FIRST CERTAINLY HAS TO BE THE OTC DRUG REVIEW. IT IS INTERESTING TO NOTE THAT EIGHT YEARS AGO TODAY THE FINAL REGUALTIONS ESTABLISHING THE OTC DRUG REVIEW WERE PUBLISHED IN THE FEDERAL REGISTER . I DON'T THINK ANYONE AT THAT TIME FORESAW THAT THE REVIEW WOULD TAKE SO LONG; IN FACT CHARLES EDWARDS, THEN THE COMMISSIONER OF THE FDA, PREDICTED THAT PROPOSED MONOGRAPHS ON THE 26 MAJOR CLASSES OF OTC DRUGS WOULD BE PUBLISHED BY DECEMBER 31, 1974, JUST TWO AND A HALF YEARS AFTER THE BEGINNING OF THE REVIEW. I THINK DR. EDWARDS CAPTURED THE GOAL OF THE REVIEW WHEN HE SAID THAT THE AMERICAN PEOPLE WANTED FULL ASSURANCE---

" THAT MARKETED OTC DRUGS CAN BE USED WITH CONFIDENCE; THAT THEIR CONTRIBUTION TO HEALTH CARE RESTS ON SCIENTIFIC EVIDENCE NOT ON UNSUBSTANTIATED CLAIMS; AND THAT THEIR VALUE LIES BOTH IN SAFETY AND EFFECTIVENESS COUPLED WITH WIDESPREAD AVAILABILITY AT REASONABLE COST."

I KNOW THAT SECRETARY HARRIS AND COMMISSIONER GOYAN HAVE COMMITTED THEMSELVES TO PURSUING VIGOROUSLY THE COMPLETION OF THE OTC DRUG REVIEW. IT IS TIME FOR FDA AND FOR YOU, THE INDUSTRY, TO RENEW YOUR DETERMINATION TO RESOLVE THE OUTSTANDING SCIENTIFIC AND POLICY ISSUES AND TO COMPLETE THE REVIEW.

A SECOND ISSUE OF PRIMARY CONCERN TO YOU IS THE FDA'S ROLE IN LABELING AND THE FTC'S ROLE IN REGULATING ADVERTISING FOR OVER-THE-COUNTER DRUGS I THINK WE CAN AGREE THAT CONSUMERS WANT AND NEED BETTER INFORMATION ABOUT THE DRUGS AVAILABLE TO THEM TODAY.. THEY WANT TO KNOW WHAT A DRUG WILL DO FOR THEM; THEY WANT TO BE WARNED ABOUT A DRUG'S INTERACTION WITH OTHER DRUGS OR WITH OTHER FOODS THEY MIGHT BE TAKING OR CONSUMING; AND THEY WANT FULL DISCLOSURE OF ALL POSSIBLE SIDE-EFFECTS BEFORE THEY CHOOSE A DRUG. MOST IMPORTANTLY THOUGH, I BELIEVE CONSUMERS WANT THIS IMFORMATION ON LABELS AND IN ADVERTISING AND THEY WANT IT TO BE ACCURATE AND IN READILY UNDERSTANDABLE TERMS. MY VIEW IS THAT THE ULTIMATE GOAL OF LABELING AND ADVERTINSING IS TO COMMUNICATE TO THE CONSUMER THAT INFORMATION NECESSARY FOR THE CONSUMER TO MAKE AN INTELLIGENT DECISION ABOUT SELF MEDICATION.

ONE LAST MATTER WHICH I KNOW CONCERNS YOU IS THE DIFFERING AND CONFLICTING STATE LAWS UNDER WHICH YOU MUST MARKET YOUR DRUGS. TO THE EXTENT THAT LABELING AND PACKAGING MUST BE CHANGED IN DIFFERENT LOCATIONS, ADDITIONAL EXPENSES WILL BE INCURRED TO MAINTAIN SEPERATE INVENTORIES AND DISTRIBUTION SYSTEMS. AT A TIME OF SKY-ROCKETING HEALTH CARE COSTS, WE MUST BE VIGILANT IN REVIEWING OUR REGULATORY MECHANISMS AND WE MUST REPEAL THOSE UNNECESSARY RESTRICTIONS AND REQUIREMENTS WHICH DO NOT CONTRIBUTE TO THE PUBLIC HEALTH. HOWEVER, A HEAVY BURDEN IS BORNE BY THOSE WHO SUGGEST THAT A STATE LEGISLATURE SHOULD NOT BE ABLE TO REGU-LATE IN WHAT IT CONSIDERS THE PUBLIC'S INTEREST. I AM SURE MY SUBCOMMITTEE WILL REVIEW THIS MATTER WITH THE SAME CAREFUL SCRUTINY IT GIVES TO ALL GOVERNMENT REGULATORY EFFORTS.

AGAIN LET ME SAY IT IS A DISTINCT PLEASURE FOR ME AND FOR MY FAMILY TO SPEND THE WEEKEND HERE WITH YOU. I WANT TO COMPLIMENT YOU FOR YOUR TENURE BECAUSE I UNDERSTAND THIS IS THE 99TH ANNUAL PROPRIETARY ASSOCIATION MEETING. I HOPE THAT NEXT YEAR YOU WILL HAVE A GRAND CELEBRATION.